(i) 16.0 to 22.5 grams per ton to provide 100 to 340 milligrams per head per day for increased rate of weight gain.

(ii) 13.5 to 16.0 grams per ton to provide 85 to 240 milligrams per head per day for reduction of incidence of liver abscesses.

(iii) 11.0 to 16.0 grams per ton to provide 70 to 240 milligrams per head per day for improved feed efficiency.

(iv) Feed continuously as sole ration to cattle fed in confinement for slaughter. Not for use in animals intended for breeding.

(4) Virginiamycin may be used in combination with:

(i) Amprolium and ethopabate as in § 558.58.

(ii) Diclazuril as in § 558.198.

(iii) Halofuginone as in § 558.265.

(iv) Lasalocid as in § 558.311.

(v) Monensin alone or with roxarsone as in § 558.355.

(vi) Salinomycin alone or with roxarsone as in § 558.550.

(vii) Semduramicin as in § 558.555.

[40 FR 13959, Mar. 27, 1975]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 558.635, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

§ 558.680 Zoalene.

(a) *Specifications.* Type A medicated article containing 25 percent zoalene.

(b) *Approvals.* See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.770 of this chapter.

(d) *Conditions of use*—(1) *Chickens and turkeys:*

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
(i) 36.3–113.5 (0.004–0.0125%).		Replacement chickens; development of active immunity to coccidiosis.	Grower ration not to be fed to birds over 14 weeks of age; as follows:

Growing conditions	Starter ration Grams per ton	Grower ration Grams per ton
Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0083%)

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Arsanilate sodium 90 (0.01%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Grower ration not to be fed to birds over 14 weeks of age; withdraw 5 days (d) before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Arsanilic acid 90 (0.01%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.	Replacement chickens; growth promotion and feed efficiency;development of active immunity to coccidiosis; improving pigmentation.	As erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable item (i).

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Replacement chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Feed for 2 d before stress and 3 to 6 d after stress; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic arsenic; feed as in subtable in item (i).
		2. Replacement chickens; as an aid in the prevention of infectious coryza; development of active immunity to coccidiosis; growth promotion and feedefficiency; improving pigmentation.	Feed for 7 to 14 d; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Replacement chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; growth promotion and feed efficiency; improving pigmentation and development of active immunity to coccidiosis.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 5 d before slaughter; as erythromycin thiocyanate; as sole source of organic arsenic; feed as in subtable in item (i).
	Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50.	Replacement chickens; growth promotion and feed efficiency;development of active immunity to coccidiosis; improving pigmentation.	As procaine penicillin; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Bacitracin methylene disalicylate 50	Replacement chickens; development of active immunity to coccidiosis; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration as in subtable in this item (i); grower ration not to be fed to birds over 14 weeks of age. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.
	Bacitracin methylene disalicylate 100 to 200	Replacement chickens; development of active immunity to coccidiosis; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration as in subtable in this item (i). To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams/ton). Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.
	Bacitracin 100 to 500.	Replacement chickens; treatment of chronic respiratorydisease (air-sac infection); blue comb (nonspecific infectious enteritis); development of active immunity to coccidiosis.	As bacitracin zinc; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Chlortetracycline 100 to 200.	Replacement chickens; development of active immunity to coccidiosis; control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Chlortetracycline 200 to 400.	Replacement chickens; development of active immunity to coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *Escherichia coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Erythromycin 4.6 to 18.5.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis.	As erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Erythromycin 92.5.	1. Replacement chickens, as an aid in the prevention of chronic respiratory disease during periods of stress; development of active immunity to coccidiosis.	Feed for 2 d before stress and 3 to 6 after stress; withdraw 24 hours (h) before slaughter; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
		2. Replacement chickens; as an aid in the prevention of infectious coryza; development of active immunity to coccidiosis.	Feed for 7 to 14 d; withdraw 24 h before slaughter; as erythromycin thiocyanate; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Erythromycin 185.	Replacement chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; development of active immunity to coccidiosis.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Hygromycin B 8 to 12.	Replacement chickens; development of active immunity to coccidiosis; control of infestation of large round worms (*Ascaris galli*) cecal worms (*Heterakis gallinae*) and capillary worms (*Capillaria obsignate*).	Grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Penicillin 2.4 to 50.	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis.	As procaine penicillin; grower ration not to be fed to birds over 14 weeks of age; feed as in subtable in item (i).
	Penicillin 2.4 to 50 plus roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Replacement chickens; growth promotion and feed efficiency; development of active immunity to coccidiosis; improving pigmentation.	As procaine penicillin; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
	Roxarsone 22.7 to 45.5 (0.0025% to 0.005%).	Replacement chickens; development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Grower ration not to be fed to birds over 14 weeks of age; withdraw 5 d before slaughter; as sole source of organic arsenic; feed as in subtable in item (i).
(ii) 113.5 (0.0125%).		Broiler chickens; prevention and control of coccidiosis.	
	Arsanilate sodium 90 (0.01%).	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%).	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus erythromycin 4.6 to 18.5.	Broiler chickens; growth prevention and control of coccidiosis; improving pigmentation.	As erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus erythromycin 92.5.	1. Broiler chickens; as an aid in the prevention of chronic respiratory disease during periods of stress; growth promotion and feed efficiency; improving pigmentation; control of coccidiosis.	Do.

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
		2. Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of infectious coryza.	Do.
	Arsanilic acid 90 (0.01%) plus erythromycin 185.	Broiler chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; as erythromycin thiocyanate; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus penicillin 2.4 to 50.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.	As procaine penicillin; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90 (0.01%) plus bacitracin 4 to 50.	Broiler chickens; prevention and control of coccidiosis; improving pigmentation; growth promotion and feed efficiency.	Withdraw 5 d before slaughter; as sole source of organic arsenic; as bacitracin methylene disalicylate.
	Bacitracin 4 to 50.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.	As bacitracin methylene disalicylate or zinc bacitracin.
	Bacitracin 4 to 50 plus roxarsone 22.7 to 45.4 (0.0025 to 0.005%).	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis; improving pigmentation.	As bacitracin methylene disalicylate or zinc bacitracin; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Bacitracin methylene disalicylate 50	Broiler chickens; prevention and control of coccidiosis; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.
	Bacitracin methylene disalicylate 100 to 200	Broiler chickens; prevention and control of coccidiosis; as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams/ton). Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.
	Bacitracin 100 to 500.	Broiler chickens; treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis); prevention and control of coccidiosis.	As zinc bacitrain.
	Chlortetracycline 100 to 200	Broiler chickens; prevention and control of coccidiosis; control of infectious synovitis caused by *M. synoviae* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d.
	Chlortetracycline 200 to 400	Broiler chickens; prevention and control of coccidiosis; control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Do not feed to chickens producing eggs for human consumption; feed continuously for 7 to 14 d.

Zoalene in grams/ton	Combination in grams/ton	Indications for use	Limitations
	Erythromycin 4.6 to 18.5.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.	As erythromycin thiocyanate.
	Erythromycin 92.5.	1. Broiler chickens; as an aid in the prevention of chronic respiratory disease during period of stress; prevention and control of coccidiosis.	Feed for 2 d before stress and 3 to 6 d after stress; withdraw 24 h before slaughter; as erythromycin thiocyanate.
		2. Broiler chicken; as an aid in the prevention of infectious coryza; prevention and control of coccidiosis.	Feed for 7 to 14 d; withdraw 24 h before slaughter; as erythromycin thiocyanate.
	Erythromycin 185.	Broiler chickens; as an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease; prevention and control of coccidiosis.	Feed for 5 to 8 d; do not use in birds producing eggs for food purposes; withdraw 48 h before slaughter; as erythromycin thiocyanate.
	Hygromycin B 8 to 12.	Broiler chickens; prevention and control of coccidiosis; control of infestation of large round worms (*Ascaris galli*) cecal worms (*Heterakis gallinae*) and capillary worms (*Capillaria obsignate*) .	
	Lincomycin 2.	Broiler chickens; increase in rate of weight gain; improved feed efficiency; as an aid in the prevention and control of coccidiosis.	Do not feed to laying chickens; to be fed as the sole ration; as lincomycin hydrochloride monohydrate provided by No. 000009 in § 510.600(c) of this chapter.
	Penicillin 2.4 to 50.	Broiler chickens; growth promotion and feed efficiency; prevention and control of coccidiosis.	As procaine penicillin.
	Penicillin 2.4 to 50 plus roxarsone 22.7 to 45.4 (0.0025 to 0.005%).	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic; as procaine penicillin.
	Roxarsone 22.7 to 45.4 (0.0025 to 0.005%).	Broiler chickens; prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaugher; as sole source of organic arsenic.
(iii) 113.5 to 170.3 (0.0125 to 0.01875%).		Turkeys; prevention and control of coccidiosis.	For turkeys grown for meat purposes only.
	Arsanilate sodium 90 (0.01%).	Turkeys; growth promotion and feed efficiency; improving pigmentation.	For turkeys grown for meat purposes only; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Arsanilic acid 90(0.01%).	do.	Do.
	Bacitracin methylene disalicylate 4–50.	Turkeys; prevention and control of coccidiosis, and increased rate of weight gain and improved feed efficiency.	For turkeys grown for meat purposes only, not to be fed to laying birds, feed continuously as sole ration until 14 to 16 weeks of age.
	Carbarsone (not U.S.P.) 277 to 340.5 (0.025% to 0.0375%).	Turkeys; prevention and control of coccidiosis; aid in the prevention of blackhead.	For turkeys grown for meat purposes only; feed continuously beginning 2 weeks before blackhead and coccidiosis are expected and continue as long as prevention of blackhead and prevention and control of coccidiosis is needed; withdraw 5 d before slaughter; as sole source of organic arsenic.
	Roxarsone 22.7 to 45.4 (0.0025% to 0.005%).	Turkeys; growth promotion and feed efficiency; improving pigmentation.	Withdraw 5 d before slaughter; as sole source of organic arsenic.

(2) *Permitted combinations.* It may be used in accordance with the provisions of this section in the combinations provided, as follows:

(i) Bambermycins in accordance with § 558.95.

(ii) Roxarsone in accordance with § 558.530.

[41 FR 11005, Mar. 15, 1976, as amended at 42 FR 18618, Apr. 8, 1977; 42 FR 20817, Apr. 22, 1977; 42 FR 36995, July 19, 1977; 51 FR 7401, Mar. 3, 1986; 52 FR 2686, Jan. 26, 1987; 55 FR 8461, Mar. 8, 1990; 57 FR 8403, Mar. 10, 1992; 57 FR 8578, Mar. 11, 1992; 61 FR 35957, July 9, 1996; 63 FR 38750, July 20, 1998; 67 FR 6868, Feb. 14, 2002]

PART 564 [RESERVED]

PART 570—FOOD ADDITIVES

Subpart A—General Provisions

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AUTHORITY: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

SOURCE: 41 FR 38644, Sept. 10, 1976, unless otherwise noted.

Subpart A—General Provisions

§ 570.3 Definitions.

(a) *Secretary* means the Secretary of Health and Human Services.

(b) *Department* means the Department of Health and Human Services.

(c) *Commissioner* means the Commissioner of Food and Drugs.

(d) As used in this part, the term *act* means the Federal Food, Drug, and Cosmetic Act approved June 25, 1936 (52 Stat. 1040 *et seq.*, as amended; 21 U.S.C. 301–392).

(e) *Food additives* includes all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. *Affecting the characteristics of food* does not include such physical effects, as protecting contents of packages, preserving shape, and preventing moisture loss. If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive. A substance that does not become a component of food, but that is used, for example, in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive.

(f) *Common use in food* means a substantial history of consumption of a substance by a significant number of animals in the United States.

(g) The word *substance* in the definition of the term *food additive* includes a food or feed or a component of a food or feed consisting of one or more ingredients.

(h) *Scientific procedures* include those human, animal, analytical, and other scientific studies, whether published or unpublished, appropriate to establish the safety of a substance.

(i) *Safe* or *safety* means that there is a reasonable certainty in the minds of